K011085

JUL - 9 2001

medamicus INCORPORATED

510(k) Summary Dated 07/06/01

General Information

Classification	Class II
Trade Name	Medamicus Guidewire Introducer Safety Needle
Submitter	Medamicus, Inc. 15301 Highway 55 West Minneapolis, MN 55447
Contact	Dennis Madison Vice President, Quality Assurance/Regulatory Affairs 763-577-2233

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Device Identification

A. Device Proprietary Name

Guidewire Introducer Safety Needle

B. Device Common Name

Guidewire Introducer Needle

C. Device Classification name and reference

Catheter Introducer
Reference §870.1340

D. Device proposed regulatory class

Class II

E. Device product code

DYB

F. Classification panel

Cardiovascular

G. Device Performance Standards

No performance standards have been promulgated under Section 514

Predicate Devices

Medical Introducer Needle from Teleflex Medical, inc. K851140
Safe Step Blood Collection Needle System from MDC Research, Ltd. K973012

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Device Description Information

Intended Use

The MedAmicus Guidewire Introducer Safety Needle incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to introduce a guidewire into the vascular system.

Device Description

The MedAmicus Guidewire Introducer Safety Needle is a single use device for percutaneous entry into the vascular system, allowing placement of a guidewire up to 0.038 inches. The device will be packaged as sterile single units. The device is designed with a shield as part of the safety needle mechanism to aid in the prevention of needle stick injuries. The needle of the device is retracted into the shield by pushing the button prior to removal of the device off the guidewire and out of the body. After retraction, the shield covers the needle tip. The device is disposed of according to routine procedure in a sharps container.

Biocompatability

Biocompatability testing on the Guidewire Introducer Safety Needle included all tests required to satisfy ISO-10993 and FDA (Memo G95-1) requirements. The needle is considered Externally Communicating with Limited Contact with Circulating Blood.

Device Performance/Product Testing

Performance data indicates that the Guidewire Introducer Safety Needle meets the functional requirements and specifications of this device.

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Technology Characteristics

The device is equivalent technologically to the devices mentioned under predicate devices above. The safety feature, which forms an integral part of this device, is the reason for this submission. The feature is an integral part of the Safe Step Blood Collection Needle System from MDC Research, Ltd. K973012. In this device the safety feature incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to access the vascular system.

Substantial Equivalence

The MedAmicus Guidewire Introducer Safety Needle incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to access the vascular system. The basic design, methods of manufacturing, and materials used are is substantially equivalent to the predicate devices, Teleflex Medical Introducer Needle for the introducer needle functions and MDC Research Safe Step Blood Collection Needle System for the sharps injury protection feature. Our application of this device is substantially equivalent to the aforementioned devices already approved for use. The clinical indications for use remain unchanged. MedAmicus believes the MedAmicus Guidewire Introducer Safety Needle is substantially equivalent to currently marketed medical introducer needles and sharps injury protection features employing the same technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dennis Madison
Vice President of Regulatory Affairs
Medamicus, Incorporated
15301 Highway 55 West
Minneapolis, Minnesota 55447

Re: K011085
Trade/Device Name: Guidewire Introducer Safety Needle
Regulation Number: 870.1340
Regulatory Class: II
Product Code: DYB
Dated: April 9, 2001
Received: April 10, 2001

Dear Mr. Madison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: MedAmicus, Inc.
510(k) Number (if known): New Submission K011085
Device Name: Guidewire Introducer Safety Needle
Indications For Use:

The MedAmicus Guidewire Introducer Safety Needle incorporates a retractable needle safety mechanism to minimize needle stick injuries when used to introduce a guidewire into the vascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011085